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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,995	04/16/2004	Niels Christian Kaarsholm	6573.204-US	9239

23650 7590 06/27/2006

NOVO NORDISK, INC.
PATENT DEPARTMENT
100 COLLEGE ROAD WEST
PRINCETON, NJ 08540

EXAMINER	
BRADLEY, CHRISTINA	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/825,995	KAARSHOLM ET AL.	
	Examiner	Art Unit	
	Christina Bradley	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-220* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-220* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

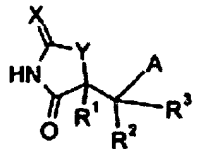
1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

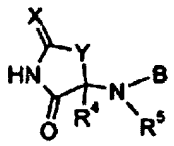
1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-57, drawn to a pharmaceutical composition comprising insulin and a zinc-binding ligand,



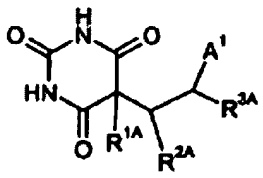
classified in class 514, subclass 4.

II. Claims 2-57, drawn to a pharmaceutical composition comprising insulin and a zinc-binding ligand,



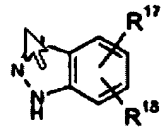
classified in class 514, subclass 4.

III. Claims 2-57, drawn to a pharmaceutical composition comprising insulin and a zinc-binding ligand,



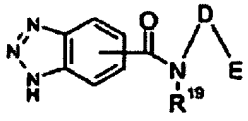
classified in class 514, subclass 4.

IV. Claims 58-104, drawn to a pharmaceutical composition comprising insulin and a zinc-binding ligand,



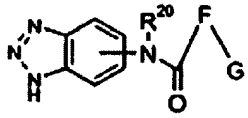
classified in class 514, subclass 4.

V. Claims 58-104, drawn to a pharmaceutical composition comprising insulin and a zinc-binding ligand,



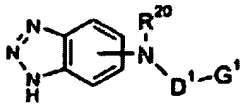
classified in class 514, subclass 4.

VI. Claims 58-104, drawn to a pharmaceutical composition comprising insulin and a zinc-binding ligand,



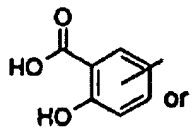
classified in class 514, subclass 4.

VII. Claims 58-104, drawn to a pharmaceutical composition comprising insulin and a zinc-binding ligand,



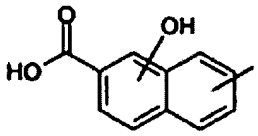
classified in class 514, subclass 4.

VIII. Claims 105-126, drawn to a pharmaceutical composition comprising insulin and a zinc-binding ligand,



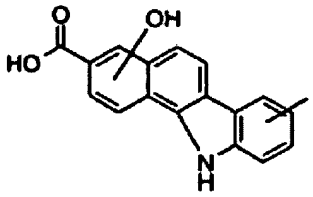
classified in class 514, subclass 4.

IX. Claims 105-126, drawn to a pharmaceutical composition comprising insulin and a zinc-binding ligand,



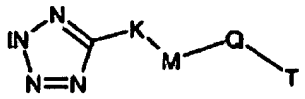
classified in class 514, subclass 4.

X. Claims 105-126, drawn to a pharmaceutical composition comprising insulin and a zinc-binding ligand,



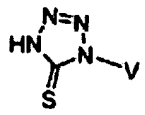
classified in class 514, subclass 4.

XI. Claims 127-170, drawn to a pharmaceutical composition comprising insulin and a zinc-binding ligand,



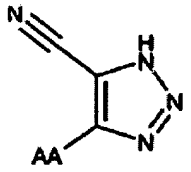
classified in class 514, subclass 4.

XII. Claims 171-186, drawn to a pharmaceutical composition comprising insulin and a zinc-binding ligand,



classified in class 514, subclass 4.

XIII. Claims 187-205, drawn to a pharmaceutical composition comprising insulin and a zinc-binding ligand,



classified in class 514, subclass 4.

XIV. Claim 219, drawn to a method for stabilizing insulin, classified in class 514, subclass 4.

XV. Claims 220, drawn to a method for treating diabetes, classified in class 514, subclass 4.

2. Claims 1 and 205-218 link(s) inventions I-XIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1 and 205-218. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the

linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

3. Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. The inventions are distinct, each from the other because of the following reasons:

5. The compounds of Groups I-XIII are related as alternative forms of the zinc-binding ligands in claims 1 and 205-218. Although the compounds share a common utility (binding to zinc and insulin) they lack a common structural core. Furthermore, a different search is required for each group.

6. Inventions I-XIII and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using

the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product such as in a method for treating diabetes. Therefore, neither invention would render the other obvious.

7. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

8. Inventions I-XIII and XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product such as in a method for stabilizing insulin. Therefore, neither invention would render the other obvious.

9. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

10. The methods of Groups XIV and XV are related inventions. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the

inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP 806.05(j). In the instant case, the method for stabilizing insulin claims do not overlap the scope of the methodfor treating diabetes claims and vice versa as evidenced by the fact the former involves te combination of chemical compounds *in vitro* and the latter involves the administration of a composition to a human patient. Additionally, the methods of Groups XIV and XV are not obvious variants of each other based on the fact that diabetes can be treated without first stabilizing insulin by the method of Group XIV. Lastly, the methods of Groups XIV and XV have materially different effects: stabilizing a protein and treating a disease, respectively. Thus, these related inventions are distinct.

11. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Election of Species

12. This application contains claims directed to the following patentably distinct species: analogues of the zinc-binding ligands of Groups I-XIII. The species are distinct for the following reasons:

13. The compounds share a common utility (binding zinc and insulin) and a common structural core (the individual structures of Groups I-XIII). However, the variable positions and substituents render these compounds related but distinct: because of their different chemical structures, the compounds do not overlap in scope, are not obvious variants of one another and

have materially different designs. For this reason, the requirement for an election of species is proper. See § MPEP 803.02.

14. Furthermore these inventions require a different field of search (see MPEP § 808.02). The variable positions in the zinc binding ligands necessitate independent search queries for each compound. To adequately search the patent and non-patent literature databases for each zinc-binding ligand would be a serious burden.

15. Regardless of which group is elected (I-XV) Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (i.e. a fully defined chemical compound) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-220 are generic.

16. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

17. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

18. This application contains claims directed to the following patentably distinct species: variants of insulin listed in claims 206-213. The species are distinct for the following reasons:

19. The variants share a common utility (effect on glucose metabolism) and a common structural core (insulin peptide sequence). However, the substitutions and modifications of the variants render these compounds related but distinct: because of their different chemical structures, the insulin variants do not overlap in scope, are not obvious variants of one another and have materially different designs. For this reason, the requirement for an election of species is proper. See § MPEP 803.02.

20. Furthermore these inventions require a different field of search (see MPEP § 808.02). The substitutions and modifications of the variants necessitate independent search queries for each protein included in this genus. To adequately search the patent and non-patent literature databases for each insulin variant would be a serious burden.

21. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (i.e. a fully defined polypeptide sequence) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-220 are generic.

22. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

23. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Notice of Possible Rejoinder

24. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

25. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

26. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

27. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

28. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Bradley whose telephone number is (571) 272-9044. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.

30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

31. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

cmb

6/23/06
ANISH GUPTA
PRIMARY EXAMINER